510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

JUL 18 2003

Submitter's Name:	St. Jude Medical, Daig Division
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 351-1453
Contact Person:	Mike Burnside
Date Submission Prepared:	19-June-2003

B. Device Information

Trade Name:	Apeel™ CS Catheter Delivery System
Common or Usual Name:	Percutaneous Catheter Introducer
Classification Name:	Percutaneous Catheter Introducer (per 21 CFR Part 870.1340)
Device Classification:	Class II (per 21 CFR Part 870.1340) Panel – Cardiovascular
Predicate Devices:	Seal-Away CS Introducer Kit, Seal-Away Hemostasis Adapter, and Alliance Catheter Delivery System St. Jude Medical, Daig Division
Device Description:	The Apeel™ CS Catheter Delivery System includes a Peelable Introducer Sheath, Dilator, Cannulator, Detachable Hemostasis Valve with Side Port, Guidewire, Syringe and Needle. The introducer kits are provided sterile, and are intended for single-use only.
Intended Use:	The Apeel CS Catheter Delivery System is intended to provide vascular access including the coronary sinus and serve as a conduit for the delivery and support of other devices where minimizing blood loss is essential.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Apeel™ CS Catheter Delivery System are substantially equivalent to the predicate devices including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division considers the Apeel CS Catheter Delivery System to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

St. Jude Medical
c/o Mike Burnside
14901 Deveau Place
Minnetonka, MN 553452

Re: K031906
Apeel CS Catheter Delivery System
Regulation Number: 870.1340
Regulation Name: Percutaneous Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 19, 2003
Received: June 20, 2003

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

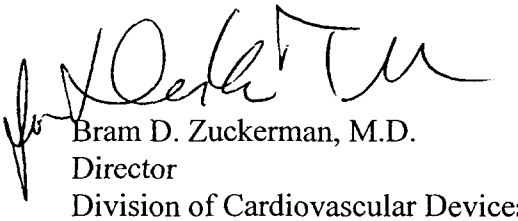
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K031906

Device Name: Apeel™ CS Catheter Delivery System

Indications for Use:

The Apeel CS Catheter Delivery System is intended to provide vascular access including the coronary sinus and serve as a conduit for the delivery and support of other devices where minimizing blood loss is essential.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031906

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)